

A FIXATION DEVICE AND METHOD OF FIXATION

Field of the invention

This invention relates to a method of fixing a first member in a position
5 relative to a second member and a fixation device for doing the same. It relates particularly but not exclusively to a fixation device and method for its use and a tool for using the fixation device.

Background to the invention

10 Bones, including joints of the body are susceptible to injury including dislocation, fracture and damage as a result of trauma, disease and degenerative change. There are many ways of reducing a fracture, employing open or closed reduction such as casting, external fixation, wiring and plating. Casting and other forms of closed reduction involves aligning the broken or
15 dislocated bone manually and setting it, usually by applying a cast. This is beneficial because it avoids the trauma of surgery and is relatively inexpensive. However, it is only suitable for relatively simple fractures and requires immobilisation of the bone which can cause stiffness and impede rehabilitation.

External fixation involves the insertion of pins into bone fragments and
20 connecting the pins using a bar or frame which sits outside the fracture site. Although this facilitates reduction of more complex fractures, it can cause irritation of the skin and soft tissue around the pins causing infection or scarring which may compromise outcomes. Open reduction and internal fixation requires extensive exposure to allow for the approximation of bone fragments and the
25 introduction of fixation devices.

In each case, the procedure must be performed with a high degree of accuracy to ensure that the bone is not damaged further and that it is correctly realigned with respect to its anatomic and biomechanical axes.

30 Summary of the invention

According to a first aspect of the present invention, there is provided a fixation device for fixing a first member in a position relative to a second member, the fixation device including:

- (a) a shaft having a head and a longitudinal axis;

- (b) a first screw portion rotatable about the axis; and
- (c) a second screw portion rotatable about the axis independently of the first screw portion;

the first and second screw portions each having an external screw thread
5 in a first thread direction and configured to engage a bore formed in the first and second members.

According to one embodiment of the fixation device:

- (a) the first screw portion is a collar screw;
- (b) the shaft includes an externally threaded portion; and
- 10 (c) the second screw portion includes a corresponding internal thread;

wherein assembly of the fixation device includes passing the shaft through the centre of the collar screw prior to threadedly engaging the second screw portion on the shaft. This arrangement may further include a lock nut having an internal thread corresponding with the shaft thread, and configured to
15 maintain the position of the second screw portion on the shaft.

According to another embodiment of the fixation device, the first screw portion is a collar screw with an opening along its length for receiving a length of the shaft.

According to another embodiment of the fixation device the head
20 includes an external screw thread in a second thread direction and the first screw portion includes a corresponding internal thread to facilitate assembly of the fixation device by screwing the first screw portion over the head. In this arrangement, the external screw thread of the head may have a leading end and a trailing end such that the trailing end terminates in a flat end so as to
25 substantially preclude engagement with a threaded member. The internal thread of the first screw portion configured to engage the external thread of the head preferably has a leading end and a trailing end such that the trailing end terminates in a flat end so as to substantially preclude engagement with a threaded member.

30 In some embodiments of the invention, the shaft may be flexible. In other embodiments, the shaft is rigid.

According to another aspect of the invention, there is provided a method of fixing a first member in a position relative to a second member, the method including the steps of:

- (a) assembling a fixation device;
- (b) forming a bore in the first and second members;
- (c) introducing the fixation device into the bore, the fixation device having:
 - (i) a shaft having head and a longitudinal axis;
 - 5 (ii) a first screw portion rotatable about the axis; and
 - (iii) a second screw portion rotatable about the axis independently of the first screw portion;

the first and second screw portions each having an external screw thread adapted to engage the bore in the first and second members;
- 10 (d) operating the fixation device in such a way that one of the first or second screw portions rotates relative to the threaded bore thereby positioning the first member relative to the second member; and
- (e) locking the fixation device in position.

15 In one embodiment of the inventive method, the step of assembling the fixation device includes passing the shaft through the centre of the first screw prior to threadedly engaging the second screw portion on the shaft.

In another embodiment, the first screw portion is a collar screw with an opening along its length for receiving a length of the shaft, and the step of assembling the fixation device includes passing the shaft through the length-wise opening of the first screw.

20

In another embodiment the head includes an external screw thread in a second thread direction and the first screw portion includes a corresponding internal thread, and the step of assembling the fixation device involves screwing the first screw portion over the head.

25

Brief description of the drawings

The invention will now be described in greater detail with reference to the embodiments illustrated in the accompanying drawings. It is to be understood that the particularity of the accompanying drawings does not supersede the generality of the preceding description of the invention.

30

Figure 1a illustrates in cross section, a fixation device being inserted into a threaded bore in accordance with an embodiment of the invention.

Figure 1b shows the sectional view of Figure 1a after operation of the fixation device to position the first member relative to the second member.

Figure 2a illustrates in cross section, a fixation device being inserted into a threaded bore in accordance with another embodiment of the invention where
5 the depth of the second member is small.

Figure 2b shows the sectional view of Figure 2a after operation of the fixation device to position the first member relative to the second member.

Figure 2c shows a sectional view of a further embodiment of the invention after operation of the fixation device for the purpose of holding the two
10 members separated by a predetermined interval.

Figure 3 illustrates in cross section, a fixation device according to an embodiment of the invention.

Figure 4a illustrates in cross section, a tool for positioning a fixation device in accordance with an embodiment of the invention.

15 Figure 4b shows the sectional view of Figure 4a with the locking mechanism activated.

Figure 5a illustrates rigid shaft suitable for use according to an embodiment of the invention.

20 Figure 5b illustrates a flexible shaft suitable for use according to another embodiment of the invention.

Figure 6 illustrates a component of an alternative embodiment of the fixation device showing the second screw portion integral with the shaft.

Figure 7a illustrates in cross section, an alternative embodiment of a first screw portion having a slot.

25 Figure 7b shows an end view of the first screw portion illustrated in Figure 7a.

Figure 8a illustrates in cross section a variation of the component illustrated in Figure 6, showing in particular, a flexible shaft.

Figure 8b illustrates an end view of the component of Figure 8a.

30 Figure 9 illustrates a component of a further embodiment of the fixation device, showing the second screw portion integral with the shaft, with an external thread on the head portion.

Figure 10a illustrates in cross section, a further embodiment of the first screw portion which an internal thread corresponding to the external thread on the head portion of Figure 9.

Figure 10b shows an end view of the first screw portion illustrated in
5 Figure 10a.

Figure 11 illustrates in cross section a variation of the component illustrated in Figure 9.

Figure 12a illustrates in cross section, a variation of the first screw portion of Figure 10a.

10 Figure 12b shows an end view of the first screw portion illustrated in Figure 12a.

Figure 13a illustrates in cross section, an alternative lock screw for use with the first screw portion of Figures 12a and 12b.

Figure 13b shows an end view of the lock screw illustrated in Figure 13a.
15

Detailed Description

Referring firstly to Figures 1a and 1b, a preferred embodiment of the invention is illustrated. A guide wire (not shown) is drilled through first member 1, henceforth referred to first bone section 1, across fracture site 2 and into
20 second member 3, henceforth referred to as second bone section 3. A first bore 4a is formed using a cannulated drill (not shown) to drill through first bone section 1, across fracture site 2 and into second bone section 3.

It is preferred that first bore 4a stops short of penetrating the far end of second bone section 3. A second larger diameter cannulated bit is used to drill
25 through first bore 4a stopping just short of fracture site 2 thus forming a second bore 4b having a larger diameter. Bore 4a may be tapped with a screw thread suitable for engaging first screw portion 5. Similarly, second bore 4b may be tapped with a screw thread suitable for engaging second screw portion 6. For simplicity, combined bores 4a and 4b will hereinafter be referred to as bore 4.
30 Fixation device 10 is then introduced into bore 4.

One embodiment of fixation device 10 is illustrated in Figure 3. It has a shaft 11, first and second screw portions 5,6 and lock nut 13. The fixation device is assembled by passing shaft 11 through first screw portion 5 which is in the form of a larger diameter collar screw with an external thread. Shaft 11 is

provided with a left-hand screw thread onto which lock nut 13 is threaded. Second screw portion 6 in the form of a smaller diameter collar screw with an internal screw thread configured to engage the left hand shaft thread. This may be assisted by use of a device such as a hex-head key to engage head 12 of
5 fixation device 10 and hold the shaft still whilst assembling the fixation device. The hex-head key may be provided in the form of tool 20 illustrated in Figure 4.

Preferably, the overall length of bore 4 is determined so that a fixation device 10 with a suitable length can be selected. Selection of a suitable fixation device may also require consideration of the diameter of the bore in the first
10 and/or second bone sections 1,3. In the embodiment illustrated in Figure 3, the effective length of the fixation device may be adjusted before inserting the fixation device into the bore, by locating the lock nut 13 and second screw portion 6 at varying positions along the shaft 11. The adjustment permissible is therefore limited by the length of the threaded portion of the shaft.

15 Shaft 11 has a longitudinal axis about which first screw portion 5 is freely rotatable. Second screw portion 6 is also rotatable about the axis of shaft 11 along the left hand screw thread. Since second screw portion 6 is threaded onto shaft 11 in one direction, rotation of screw portion 6 in the other direction will also rotate shaft 11. It follows that rotation of the shaft will also effect rotation of
20 the second screw portion. However, first screw portion 5 is not threaded onto shaft 11 and therefore rotates freely about the shaft, independently of second screw portion 6.

As can be seen in Figure 3, first and second screw portions 5,6 each have an external screw thread which is adapted to engage bore 4 in the first
25 and second bone sections 1,3. The pitch of the external screw thread on first screw portion 5 is equal to the pitch of the external screw thread on second screw portion 6. This enables, both screw portions to undergo the same amount of linear translation for each degree of rotation of the fixation device, regardless of screw portion diameter.

30 Fixation device 10 is introduced into bore 4 over a guide wire (not shown) which aids in maintaining alignment of the bore 4 in first and second bone sections 1,3. Introduction of fixation device 10 may be aided by use of a specially designed tool such as that which is illustrated in Figure 4.

Referring now to Figure 4, tool 20 has a first engaging portion 21, a second engaging portion 22 and a locking mechanism 23 as well as a handle 24. First engaging portion 21 is provided in the form of an outer shaft for engaging part of first screw portion 5. Second engaging portion 22 is provided in the form of an inner shaft for engaging part of second screw portion 6 and is operable independently of first engaging portion 21. Locking mechanism 23 can be used to lock movement of first engaging portion 21 relative to second engaging portion 22. For simplicity, first engaging portion 21 will henceforth be referred to as outer shaft 21 and second engaging portion 22 will hence forth be referred to as inner shaft 22.

Preferably, tool 20 is cannulated with a two stage hex-head design. That is, outer and inner shafts 21,22 have a hexagonal cross-section so that inner shaft 22 engages a corresponding hex-head recess in head 12 and outer shaft 21 engages with a hex-head inner aperture provided in first screw portion 5. It is to be understood that other suitable tool-head designs may be employed. Security screw heads are some existing designs which may be suitable.

With locking mechanism 23 activated, movement of inner shaft 22 relative to outer shaft 21 is fixed. Therefore, rotation of handle 24 will facilitate rotation of outer and inner shafts 21,22 together. Accordingly, first and second screw portions 5,6 will rotate together. This enables assembled fixation device 10 to advance into bore 4 with second screw portion advancing through first bone section 1, across fracture site 2 and into a portion of bore 4 formed in second bone section 3. In one embodiment, fixation device 10 is advanced until it reaches the end of bore 4. Since the pitch of the external threads on first and second screw portions 5,6 are equal there is no relative movement of first bone section 1 relative to second bone section 3 during introduction of fixation device 10. The pitch of screw thread on first and second screw portions 5,6 may be selected based on several factors such as the length of the bore and the softness of the bone being positioned. For example, a more coarse thread may be desirable when the screw portion is being screwed into softer bone.

Once fixation device 10 has been introduced into bore 4, that is, it is located *in situ*, locking mechanism 23 on tool 20 is released so that outer shaft 21 rotates independently of inner shaft 22. Holding outer shaft 21 still, inner shaft 22 engages head 12 and is rotated clockwise. This causes second screw

portion 6 to advance into second bone section 3 having the effect of drawing it toward first bone section 1 (since first screw portion 5 is not moving in the first bone section) thereby closing fracture site 2. This is illustrated in Figure 1b. When the desired relative positioning of the bone sections has been achieved,
5 tool 20 is removed and fixation device 10 is locked into position.

To achieve further closure of the fracture site, tool 20 may be used to engage first screw portion 5 independently of shaft 11. First screw portion 5 may then be rotated counter-clockwise to draw the first screw portion outward of the bore drawing head 12 and therefore shaft 11 and second screw portion 6
10 with it, closing the gap between first and second bone sections 1,3. This is described in further detail below, in the context of a variation on the above method.

Preferably fixation device 10 is locked into position using a cannulated lock screw 14 which is introduced over the guide wire and screwed inside an
15 internal diameter of first screw portion 5. This may be achieved using a hex-head tool. Preferably, cannulated lock screw 14 is provided with a hex-head socket with the same dimension as the hex-head socket in head 12. Therefore, inner shaft 22 of tool 20 is also suitable to fasten lock screw 14 and lock fixation device 10 into position. Once lock screw 14 has been advanced into first screw
20 portion 5 so that it no longer projects beyond first screw portion 5, outer shaft 21 of tool 20 may be used to engage and hold first screw portion 5 still whilst lock screw 14 is advanced further (if necessary) into the first screw portion. Advancement of lock screw 14 should cease when it is tightened against head 12. Once lock screw 14 is suitably positioned, the guide wires are removed and
25 the procedure is concluded.

A variation of the above-described method is provided and may be suitable where the depth of second bone section 3 is small and movement of second screw portion 6 within the second bone section 3 should be minimised. Such an embodiment is illustrated in Figures 2a and 2b. Bore 4b is drilled
30 stopping just short of the far cortex of second bone section 3. Fixation device 10 is selected with a shaft length which is less than the total overall length of bore 4. Fixation device 10 is introduced into bore 4 over the guide wire so that second screw portion 5 is only just past fracture site 2 in second bone section 3. Using tool 2 with inner shaft 22 held still, outer shaft 21 is rotated counter

clockwise causing first screw portion 5 to retract in the portion of bore 4 located in first bone section 1. Since the location of second screw portion 6 is fixed in second bone section 3, this has the effect of drawing first bone section 1 toward second bone section 3, thereby closing fracture site 2.

5 When the fracture site 2 is closed, locking mechanism 23 is activated and outer and inner shafts 21,22 are rotated together advancing fixation device 10 further into bore 4. Locking mechanism 23 can then be released and the tool used again to rotate outer shaft 21 in an anti-clockwise direction, retracting first screw portion 5. This procedure with outer and inner shafts 21,22 coupled and
10 uncoupled is repeated until first and second bone sections 1,3 are positioned as required.

 In another embodiment, peripheral guide wires are introduced in series with the central guide wire prior to drilling and tapping the bore in the first and second members and inserting the fixation device. This assists in controlling
15 potential torque reactions that may develop between the first and second members and other bone fragments particularly when the invention is used in a surgical environment.

 It is to be understood that use of the inventive method and apparatus should not be limited to closing of fracture sites. Figure 2c shows a further
20 embodiment where first and second bone sections 1,3 have been positioned using fixation device 10 without completely closing fracture site 2.

 It is to be understood that the methods exemplified herein describe only some of the ways in which the invention may be performed. As an alternative, the first and second bore portions 4a and 4b may have the same diameter, eliminating the need to use 2 cannulated drill bits to form the bore 4.
25 Accordingly, first and second screw portions 5,6 can also share the same diameter.

 As a further alternative, second screw portion may be welded, glued or otherwise attached to shaft 10 or may be integral with the shaft itself as
30 illustrated in Figure 6. Clearly this eliminates the need to assemble lock nut 13 and second screw portion 6 on shaft 13. However this does not permit shortening of the length of the fixation device. It is to be understood that using a screw thread to fasten second screw portion 6 to shaft 10 (and a lock nut 13 to retain the position of the second screw portion on the shaft) facilitates

adjustment of the overall length of fixation device 10 and may therefore be favourable as it provides modularity, potentially reducing the range of sizes in which the fixation device may need to be manufactured. This modularity also allows each fixation device to be sized just prior to use, on a case by case basis. Although it may be preferred that shaft 10 is rigid as illustrated in the embodiment of Figure 5a, it may also be flexible as illustrated in Figures 5b and 8a.

Referring now to Figures 7a and 7b, there is shown a sectional view and end view of an alternative embodiment of the first screw portion, indicated by reference numeral 30. Notably, first screw portion 30 has an elongate opening 31 extending along the length of screw portion 30 and having a width which is sufficient for receiving shaft 11. This allows the fixation device to be assembled by slotting the first screw portion 31 over the shaft rather than by inserting the end of the shaft into the hollow centre of the first screw portion and sliding the first screw portion along the shaft as is necessary for the embodiment illustrated in Figure 3. Clearly this is advantageous because it eliminates the need to remove the lock screw 13 and second screw portion 6 from the shaft, should a first portion with a different diameter be required. First screw portion 30 also facilitates assembly of the fixation device where second screw portion 6 is integral with shaft 11 as is the case in Figure 6.

First screw portion 30 also provides a socket 32 for engaging a tool having hex head, such as outer shaft 21, to rotate first screw portion 30 within the bore 4. An internal screw thread 33 configured to receive lock screw 14 is also provided. Preferably internal screw thread 33 is a right handed screw thread.

Figures 8a and 8b illustrate a variation of the shaft illustrated in Figure 6 where the shaft is flexible. In this embodiment, shaft 11 includes a hollow 35 into which an elongate portion of a tool may be inserted. The tool engages second screw portion 6 at engaging region 36 to rotate and advance second screw portion 6 into second bone section 3. For a hex-head shaped tool, engaging region 36 may be provided in the form of a hex-shaped socket as illustrated in Figure 8b.

Figures 9 and 10a and 10b illustrate components of a further embodiment of the fixation device. First screw portion shown at generally at 40

includes an internally threaded portion 41 providing a left hand screw thread. Shaft 11 has a head portion which includes an external left hand thread 44 corresponding with internal thread portion 41. This allows the fixation device to be assembled by screwing first screw portion 40 over threaded head 44 as an
5 alternative to the assembly method used for the embodiments illustrated in Figures 3 and 7a and 7b. Notably, internally threaded portion 41 terminates just inside first screw portion 40. Cavity 45 has no screw thread and allows the head of the shaft to rotate freely therein.

Preferably, the trailing end of the external screw thread 44 on the head
10 ends abruptly in a flat edge rather than in a bevel. This prevents thread 44 from re-engaging with the corresponding internal screw thread 41 of first screw portion 40 and becoming removed therefrom. Similarly, it is desirable to terminate trailing end of internal screw thread 41 of the first screw portion in a flat edge (i.e. with no bevel) to further preclude re-engagement of screw threads
15 41 and 44 and removal of the head from the first screw portion.

First screw portion 40 also provides a socket 42 for engaging a tool having hex head, such as outer shaft 21, to rotate first screw portion 40 within the bore 4. An internal screw thread 43 configured to receive a lock screw is also provided. Preferably internal screw thread 43 is a right hand screw thread.
20 It is also desirable that the innermost end of internal screw thread 43 also terminates in a flat end, without a bevel to further prevent engagement between the external thread 44 of the head and internal thread 43 of the first screw portion 40. The fact that external thread 44 and internal thread 43 are in opposite directions further prevents the head from engaging the internal thread
25 43 and working its way out of first screw portion 40. This is advantageous when the fixation device is used as a distraction device, as well as a fracture compression device.

Figures 11, 12a, 12b, 13a and 13b illustrate further variations of the components illustrated in Figures 9, 10a and 10b. Internal thread 51 of the first
30 portion is a left hand thread configured to engage with corresponding external thread 54 of the head. First screw portion 50 also includes engaging region 52 for engaging a tool to rotate the first screw portion within the first bone section. A lock screw 58 illustrated in Figures 13a and 13b, has a right hand thread corresponding with internal thread 53 of the first screw portion 50 and an

engaging portion 59 configured to engage a tool, preferably having a hex-head as illustrated in the cross section of Figure 13b. Lock screw 58 is screwed into the first screw portion along internal thread 53 and will eventually be in abutment with head 12 of shaft 11.

5 Advantageously, independent rotation of first and second screw portions facilitates multi-stage positioning of first and second bone sections 1,3 and therefore multi-stage closure or positioning of bone sections 1,3 around fracture site 2. The position of first bone section 1 relative to second bone section 3 can be changed by rotating the first and/or second screw portions 5,6 without
10 advancing the entire fixation device further into the bore or changing the overall length of the fixation device. A further advantage provided by the present invention is that the fixation device remains entirely within the confine of the bore. Therefore, it is ideal for use in intraarticular fixation. Moreover, when the fixation device is cannulated and used in conjunction with a guide wire, the
15 invention is highly suited to the closed management of fractures by percutaneous techniques.

 A primary application for the present invention is in the field of orthopaedic surgery, as a means of fixation between two bones, one fractured bone or a bone and plate or other such device. There are many different areas
20 in the body and different areas of surgery in which the inventive method and apparatus may be useful. However, it is to be understood that the principles of the invention are also suitable for use in fields outside surgery and medicine in general. Such fields may include but are not limited to carpentry, joinery and metal fabrication.

25 It is to be understood that various modifications, additions and/or alterations may be made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.